

## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address. COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044.234	01/11/2002	Paola Elisabettini	DI-5782	8974
29200	7590 03/26/2003			
BAXTER HEALTHCARE CORPORATION			EXAMINER	
RENAL DIVI I BAXTER P		CHOI, FRANK I		
DF3-3E	ARRWAI			
DEERFIELD, IL 60015			ART UNIT	PAPER NUMBER
Ź			1616	8
			DATE MAILED: 03/26/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

•		Application No.	Applicant(s)		
		10/044,234	ELISABETTINI ET AL.		
	Office Action Summary	Examiner	Art Unit		
		Frank I Choi	1616		
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status	Posponsive to communication(s) filed on				
1) <u> </u>	Responsive to communication(s) filed on This action is <b>FINAL</b> . 2b) This	—· is action is non-final.			
3)□	,		osecution as to the merits is		
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims					
4) Claim(s) 1-64 is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
6) Claim(s) is/are rejected.					
7)	Claim(s) is/are objected to.				
•—	Claim(s) <u>1-64</u> are subject to restriction and/or e	election requirement.			
	on Papers				
	The specification is objected to by the Examine				
10)[1	The drawing(s) filed on is/are: a) ☐ accept				
44)[7] 7	Applicant may not request that any objection to the		·		
11)[	The proposed drawing correction filed on		ved by the Examiner.		
If approved, corrected drawings are required in reply to this Office action.					
12) The oath or declaration is objected to by the Examiner.					
Priority under 35 U.S.C. §§ 119 and 120					
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:					
1. Certified copies of the priority documents have been received.					
	Certified copies of the priority documents		on No.		
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of the certified copies not received.					
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).					
a) ☐ The translation of the foreign language provisional application has been received.  15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.					
Attachment(s)					
2) Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal F	(PTO-413) Paper No(s) Patent Application (PTO-152)		

Application/Control Number: 10/044,234

Art Unit: 1616

## **DETAILED ACTION**

## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-16, drawn to a two part dialysis solution comprising a first component containing bicarbonate and a second component comprising electrolyte in which both components contain sodium.
- II. Claims 17-29, drawn to a two part dialysis solution comprising a first component containing bicarbonate and a second component comprising electrolyte in which the first component does not contain potassium and the second component contains potassium.
- III. Claims 30-43, drawn to a two part dialysis solution comprising a first component containing bicarbonate and a second component comprising electrolyte in which both components contain potassium.
- IV. Claims 44-54, drawn to a method for hemofiltration comprising a two part dialysis solution comprising a first component containing bicarbonate and a second component comprising electrolyte in which both components contain sodium.
- V. Claims 55-63, drawn to a method for hemofiltration comprising a two part

  dialysis solution comprising a first component containing bicarbonate and a

  second component comprising electrolyte in which the first component does not

  contain potassium and the second component contains potassium.

Application/Control Number: 10/044,234

Art Unit: 1616

VI. Claims 64-72, drawn to a method for hemofiltration comprising a two part dialysis solution comprising a first component containing bicarbonate and a second component comprising electrolyte in which both components contain potassium.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and III, and inventions IV, V and VI, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown:

(1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the product as claims can be practiced with another materially different product as evidenced by the different product claims and the product as claimed can be used as an irrigation fluid.

Inventions II and V and III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions cannot be used together as II and V cannot contain potassium in the first component whereas III and VI must contain potassium in the first component.

Inventions I and IV, and II and V and III and VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations

Application/Control Number: 10/044,234

Art Unit: 1616

(MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because Inventions I and IV may or may not contain potassium in either component. The subcombinations II and V and III and VI have separate utility as evidence by the claiming of said inventions in independent claims.

Because these inventions are distinct for the reasons given above and the search required for each of the Inventions is not required for the other as indicated above and that product inventions do not require the search of methods of use, and, as such, would constitute an undue burden on Examiner, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

## Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

March 24, 2003

S. MARK CLARDY
PATENT EXAMINER
GROUP 1200

Ando